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EXAMINER

DROESCH, KRISTEN L

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,371

Applicant(s)

BARDY ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-164 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 9-11, 15-19, 38, 39, 54, 87-89, 93-97, 125 and 153 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3, 20, 21, 32, 44, 48, 59, 60, 75, 98, 99, 110, 122, 130 and 150.

Continuation of Disposition of Claims: Claims rejected are 1, 2, 4-8, 12-14, 22-31, 33-37, 40-43, 45-47, 49-53, 55-58, 61-74, 76-86, 90-92, 100-109, 111-121, 123-124, 126-129, 131-149, 151, 152 and 154-163.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species X in Paper No. 9 is acknowledged.
2. Claims 3, 20-21, 32, 44, 48, 59-60, 75, 98-99, 110, 122, 130, and 150 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Drawings

3. The drawings are objected to because in Figure 23 B element number 228 is missing and not shown as it is in Fig. 23A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim number 122 was missing between claims 121 and 123. Misnumbered claims 123-164 been renumbered 122-163 respectively. Claim 11 is objected to because of the following informality: "further wherein" in line 2.

Claim 129 is objected to because of the following informality: "at lease one" in line 6.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 40 recites the limitation "the circular arc" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner suggests making claim 40 dependent on claim 39 and claim 41 dependent on claims 28 or 38.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 4-5, 8, 12, 22, 25-31, 33-34, 37, 40, 43, 45-47, 49-50, 53, 55, 58, 61-62, 65-68, 71-74, 76-77, 80, 83, 85-86, 90, 100, 103-109, 111-112, 115-121, 123-124, 126-129, 131-132, 135-137, 140-143, 146-149, 151-152, 154-158, and 160-163 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (5,385,574).

The functional language and introductory statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claim 1, Hauser et al. shows an ICD comprising a housing, wherein at least a portion of the housing is curved (the edges); an electrical circuit (18) and at least one electrically conductive surface (electrode) integrally positioned on a portion of the housing (14, 14', 52, 62, 64, 66, 80) and coupled to the electrical circuit (Figs. 1, 3, 8, and 11).

Regarding claim 2 and 47, 74, and 129, Hauser et al. shows the housing comprises at least one electrically insulated surface (82) or nonconductive material.

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With respect to claims 4, 33, 49, 76, 111, 123, 131, and 151, it is inherent that the housing comprises a material that can be sterilized, since a surgeon would not place an implantable device in a patient without the item first being sterilized due to the serious risk of infection.

Regarding claims 5, 34, 50, 77, 112, and 132, Hauser et al. shows the housing comprises a ceramic material (Col. 6, lines 54-65).

With respect to claims 8, 37, 53, 85-86, 118, 124, 149, and 152, Hauser et al. shows the housing comprises a mixture of ceramic and titanium (Col. 6, lines 49-60).

Regarding claims 12, 40, 55, 62, 80 90, and 137, Hauser et al. shows the curved portion (the edges) of the housing comprises a circular arc approximately 1 radians to 180 radians in length (Fig. 11).

With respect to claims 22, 68, 71, 83, 100, 143, and 158, Hauser et al. shows the electrical circuit can provide cardioversion defibrillation (Abs).

Regarding claims 25, 29, 103, 107, 119 146, and 161, Hauser et al. shows the electrically conductive surface (electrode) (14, 14', 52, 62, 64, 66, 80) can emit energy for shocking the patient's heart (Col. 2, lines 29-34).

Regarding claims 26-27, 30-31, 72-73, 104-105, 108-109, 120-121, 147-148, and 162-163 Hauser et al. shows the electrically conductive surface can receive sensory information (Col. 7, lines 9-15).

With respect to claim 28, Hauser et al shows the at least one electrode (62, 64) is integrally disposed in the at least one curved portion of the housing such that the at least one electrode is maintained in a predetermined relationship subcutaneously over the patient's ribs

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and cardioversion defibrillation circuitry located within the housing and coupled to the at least one electrode (Figs. 8, 11).

Regarding claims 43, 115, and 126, Hauser et al. shows the predetermined relationship is with respect to the patient's heart.

With respect to claims 45, 117, 128, and 160, Hauser et al. shows the circuitry provides waveform cardiac pacing for a patient's heart (Col. 5, lines 27-32).

Regarding claim 45, Hauser et al. shows a housing having a top surface and a bottom surface, wherein at least a portion of the bottom surface is non-planar (the edges) and wherein the electrode can provide an effective electric field for myocardial cardioversion and defibrillation (Col. 2, lines 29-34).

With respect to claims 58, 65, 140, and 154-155, Hauser et al. shows the bottom surface and top surface of the housing are substantially smooth (Fig. 11)

Regarding claims 61, and 136, Hauser et al. shows a portion of the top surface of the housing is substantially non-planar (the edges) (Fig. 11).

With respect to claims 66, 141, and 156, Hauser et al. shows the bottom surface (surface that faces the heart) further comprises a proximal end and a distal end, wherein an electrode (62) is integrally positioned at the proximal end (left) of the bottom surface (Fig. 11).

Regarding claims 67, 142, and 157, Hauser et al shows a second electrode (64) is integrally positioned at the distal end (right) of the bottom surface (Fig. 11).

With respect to claim 106, Hauser et al. shows non conductive housing and the at least one electrode (62, 64) is integrally disposed on the housing such that the at least one electrode is maintained in a predetermined relationship subcutaneously over the patient's ribs and

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cardioversion defibrillation circuitry located within the housing and coupled to the at least one electrode (Fig. 8).

Regarding claim 135, Hauser et al. shows a portion of the top surface of the housing is substantially planar (Fig. 11).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 6-7, 35-36, 51-52, 78-79, 113-114, and 133-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) as applied to claims 5, 34, 50, 77, 112, and 133 above and further in view of Mech et al. (2002/0120296). Hauser et al. discloses the claimed invention except for specifically showing the type of ceramic used. Mech et al. teaches that implantable medical devices are typically made of ceramics including zirconia, stabilized zirconia, partially stabilized zirconia, tetragonal zirconia, magnesia stabilized zirconia, ceria stabilized zirconia, yttria stabilized zirconia, and calcia stabilized zirconia (Para. 0003). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize zirconia, partially stabilized zirconia or stabilized zirconia for the ceramic of Hauser since it is typically used for constructing implantable medical devices.

12. Claims 13-14, 41-42, 56-57, 63-64, 81-82, 91-92, and 138-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574). Hauser et al. discloses the claimed invention except for the curved portion, non-planar bottom surface, or non-planar top

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surface comprising an elliptical curve or a nonsymmetrical arc. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the curved portion, non-planar bottom surface, or non-planar top surface as taught by Hauser et al. with an elliptical curve or nonsymmetric arc, since applicant has not disclosed that these particular types of curves provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any curve such as the curve taught by Hauser et al. for forming the edge of the curved portion, non-planar bottom surface, or non-planar top surface.

13. Claims 23-24, 69-70, 84, 101-102, 144-145, and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (5,385,574) as applied to claims 1, 22, 46, 68, 83, 85, 100, 130, 144, and 159 above and further in view of Mower (5,871,506). Hauser et al. discloses the claimed invention except for setting forth the specific waveforms utilized in cardiac pacing. Mower teaches using biphasic waveforms for cardiac pacing in order to improve cardiac conduction and contraction (Col. 2, lines 42-53). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to apply monophasic, biphasic pacing pulses as Mower teaches with the device of Hauser et al. since they are well known in the art and the application of biphasic pulses provides the advantage of improving cardiac conduction and contraction.

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Double Patenting

14. Claims 1, 46, 74, 106, and 129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 51, 81, and 83 of copending Application No. 09/940373. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

15. Claims 9-10, 18-19, 38-39, 54, 87-89, 93-97, 125, and 153 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claims 11, 15-17 would be allowable if rewritten to overcome the minor informalities objection(s), set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

17. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to teach or suggest an ICD with at least one electrode (or electrically conductive surface) positioned on the housing which comprises a first segment and a second segment each having a an insulating plate at the end and a conductive plate coupled to the insulating plate and where the conductive plates of the first and second segments are coupled to one another to form a unitary implantable device.

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Conclusion

18. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

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